PART 58-1 OF 10 NYCRR
CLINICAL LABORATORIES

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Section 58-1.1 Permit.

(a) Permit means a clinical laboratory or blood bank permit issued by the Commissioner of Health. No clinical laboratory or blood bank shall be issued a permit in a category unless:

(1) its director or assistant director holds a certificate of qualification in the category for which the permit is sought;

(2) the laboratory has been inspected and has corrected any deficiencies found; and

(3) the laboratory has successfully participated in all required proficiency examinations or remedial activities in the categories sought.

(b) A clinical laboratory or blood bank shall perform only those tests that are within the categories stated on its permit. Specimens for all other tests shall be referred to a clinical laboratory with a permit in the appropriate category. Categories of tests shall be designated according to the following procedures or specialties:

(1) one or more of the following subspecialties of microbiology: bacteriology, virology, mycology, parasitology, and mycobacteriology;
(2) hematology;

(3) blood services-diagnostic immunohematology, collection and/or transfusion;

(4) one or more of the following subspecialties of clinical biochemistry: clinical chemistry, blood pH and gases, endocrinology, and therapeutic substance monitoring/quantitative toxicology;

(5) histopathology or one or more of the following subspecialties: dermatopathology and oral pathology;

(6) cytopathology;

(7) urinalysis;

(8) one or more of the following subspecialties of toxicology: drug analysis-qualitative, blood lead and erythrocyte protoporphyrin, forensic toxicology, and chlorinated hydrocarbons;

(9) cytogenetics;

(10) human immunodeficiency virus (HIV) testing;

(11) histocompatibility;

(12) diagnostic immunology;

(13) cellular immunology;

(14) oncofetal antigens; and

(15) other specific tests or procedures as designated by the department.

(c) In performance of laboratory procedures stated on its permit, a blood bank shall meet the appropriate requirements in Subpart 58-2 and sections 58-1.2 through 58-1.6, 58-1.9, 58-1.10 and 58-1.11 of this Subpart.

(d) A provisional permit shall be available which shall be valid for a period determined by the Department to be sufficient to enable the department to assess the proficiency of the laboratory in the categories sought. The provisional permit may be renewed pending issuance or denial of a permit if initial proficiency test results are
inconclusive.

(1) A clinical laboratory or blood bank initially applying for permit may be issued a provisional permit when the laboratory meets the following conditions:

(i) a valid and complete permit application has been filed; and

(ii) application and reference fees have been paid; and

(iii) the director or assistant director holds a Certificate of Qualification in all categories sought; and

(iv) the laboratory has been inspected by the department and has provided satisfactory evidence of correction of any deficiencies found.

(2) Provisional permits shall not be available in the categories of cytogenetics-general, mycology, mycobacteriology, human immunodeficiency virus screening and/or confirmatory testing, or virology.

(3) A clinical laboratory or blood bank which has failed to demonstrate its proficiency in testing specimens in a category may, after successful participation in a remediation program, including proficiency testing, be granted a provisional permit.

(4) If the director or any owner of the laboratory applying for a provisional permit has ever directed or owned a laboratory which has had its permit revoked, suspended, limited or annulled, or which has an enforcement proceeding against it pending at the time of application for a provisional permit, a provisional permit shall not be issued. Owner shall include any individual, corporation, partner or other person holding a 10 percent or more interest in the laboratory.

(5) Provisional permits may be revoked, suspended, limited or annulled, or the holder thereof may be censured, reprimanded or otherwise disciplined in accordance with the Public Health Law, including section 577 thereof.

(6) A provisional permit in a category may be converted to a permit when the laboratory has demonstrated to the satisfaction of the department its proficiency in testing specimens in that category.

58-1.2 Laboratory director.

(a) The director shall serve the laboratory full time, or on a regular part-time basis. Regular part-time basis shall mean assumption of full responsibility for direction and technical operation of the laboratory, including adherence to the department's quality control standards and training of personnel performing the testing. If he serves
on a regular part-time basis, he shall not serve as director of more than two clinical laboratories, within or outside New York State, or more than one clinical laboratory and one blood bank or more than two blood banks. Where a laboratory and a blood bank are on the same premises and are under the supervision of the same director, such laboratory and blood bank shall be deemed one laboratory for the purpose of this subdivision. Notwithstanding the foregoing provisions of this subdivision, if the commissioner finds that more than two laboratories are required to serve the needs of an area and the total volume and the types of laboratory service provided by the several laboratories are not such as to require the services of more than one director, he may authorize an individual to direct more than two laboratories or blood banks or combinations thereof. Such authorization must be renewed at least every two years. The commissioner may also make an exception where the additional directorships involve only blood-holding facilities as defined in section 58-2.1(i) of this Part.

(b) Commensurate with the laboratory workload, scope and complexity of the testing procedures carried out, qualifications of on-site personnel, proximity to another laboratory under identical directorship, and availability of alternate monitoring and communication capabilities, the director shall spend an adequate amount of time in the laboratory to direct and supervise the technical performance of the staff and shall be readily available for personal or telephone consultation. The adequacy of the amount of time a laboratory director is present and in active direction shall be determined by the department based on the factors enumerated above, results of on-site inspections and proficiency testing and documentation of the director's full responsibility for direction and technical operation. Attendance records may be required to document the adequacy of the director's presence.

(c) The director shall be responsible for performance of all tests carried out in the laboratory, adherence to the department's quality assurance standards for such tests, and accurate reporting of test results.

(d) The director shall be responsible for ensuring the employment of qualified laboratory personnel, evaluation of job performance of such personnel and their inservice training.

(e) If the director's employment terminates or he is temporarily absent, arrangements shall be made for a qualified temporary director, which arrangements must receive the prior approval of the department. An assistant director who holds a certificate of qualification to be a director of a clinical laboratory or blood bank in the appropriate category may act for the director in the director's absence, and at such time shall fully discharge the duties and responsibilities of the director.

(f) When the director's employment terminates, for whatever reason, both the
owner and the director of the laboratory, or chief executive office of the facility, shall notify the department in writing prior to the termination.

(g) In case of death or physical and/or mental incapacitation of the director, the owner or the chief executive officer must notify the department within 72 hours of such event.

58-1.3 Clinical laboratory supervision.

(a) A clinical laboratory shall have one or more supervisors who, under the general direction of the laboratory director, supervise technical personnel and reporting of findings, perform tests requiring special scientific skills, and, in the absence of the director, are responsible for the proper performance of all laboratory procedures.

(b) A laboratory director who qualifies pursuant to the provisions of section 19-2 of this Title shall also be deemed qualified as a supervisor.

(c) Depending upon the size and functions of the laboratory, the department may authorize the laboratory director to also serve as the supervisor of the laboratory.

(d) The supervisor shall be on the laboratory premises during all hours in which tests are performed. An exception to the on-premises requirement shall be applicable with respect to the performance of procedures required for emergency purposes; provided, that the person performing the test qualifies as a medical technologist pursuant to the provisions of section 58-1.5(b) of this Subpart, the results of his work are reviewed by the supervisor or director during his or her next duty period, and a record is maintained to reflect the actual review.

(e) An individual who qualifies as a supervisor pursuant to provisions of section 58-1.4(d) of this Subpart, shall supervise technical personnel in the specialty of cytology only.

58-1.4 Qualifications of laboratory supervisor. The laboratory supervisor must meet one of the following requirements:

(a) The supervisor is a physician licensed to practice medicine or osteopathy in the State of New York or an individual who has earned a doctoral degree from an accredited institution with a chemical, physical or biological science as his major subject (accredited, as used herein, refers to accreditation by a nationally recognized accrediting agency or association, as determined by the United States Commissioner of Education). The supervisor shall, subsequent to graduation, have had at least two years' experience in one of the laboratory specialties in a clinical laboratory or blood
bank having a director at the doctoral level. The clinical laboratory or blood bank shall be part of a hospital, a health department, university, medical research institution, or other institution which provides equivalent training.

(b) The supervisor holds a degree of master of arts or master of science from an accredited institution with a major in one of the chemical, physical or biological sciences and, subsequent to graduation, has had at least four years of pertinent laboratory experience of which not less than two years have been spent working in the designated laboratory specialty in a clinical laboratory having a director at the doctoral level. The clinical laboratory or blood bank shall be part of a hospital, a health department, university, medical research institution, or other institution which provides equivalent training.

(c) The supervisor is qualified as a medical technologist pursuant to the provisions of section 58-1.5(b) of this Subpart and has had at least six years of pertinent clinical laboratory experience subsequent to qualifying of which at least two years have been spent working in a clinical laboratory having a director at the doctoral level. The clinical laboratory or blood bank shall be part of a hospital, university, health department, medical research institution or other institution which provides equivalent training.

(d) The supervisor is qualified as a cytotechnologist pursuant to the provisions of section 58-1.5(c) of this Subpart and subsequent to qualifying, has had at least four years of pertinent clinical laboratory experience in cytotechnology in a laboratory having a doctoral level director qualified in cytopathology. The clinical laboratory shall be part of a hospital, health department, university, medical research institution, or other institution which provides equivalent training.

(e) With respect to individuals first qualifying prior to April 1, 1972, an exception to the requirements in subdivision (a), (b) or (c) of this section may be made if:

(1) the supervisor was performing the duties of a clinical laboratory supervisor at any time between July 1, 1961 and September 1, 1971; and

(2) the supervisor has had at least 15 years of pertinent clinical laboratory experience prior to September 1, 1971: provided, that a minimum of 30 semester hours of credit toward a bachelor's degree with a chemical, physical or a biological science as his major subject; or 30 semester hours in an approved school of medical technology shall reduce the required years of experience by two years, with any additional hours further reducing the required years of experience at the rate of 15 hours for one year; and

(3) he has performed the duties of a supervisor for at least two years during the qualifying 15 years in:
(i) a clinical laboratory having a director at the doctoral level, of a hospital, university, health department or medical research institution; or

(ii) in a laboratory approved under the Medicare supplementary medical insurance program, provided also, that where qualifying years in a laboratory described in subparagraph (i) of this paragraph are obtained after January 30, 1969, the laboratory meets applicable conditions under the Medicare health insurance program, or, under title 42, Code of Federal Regulations, part 74, the latter being the regulations issued pursuant to the Federal Clinical Laboratories Improvement Act of 1967.

58-1.5 Duties and qualifications of clinical laboratory technical personnel.

(a) Duties of technologist. The laboratory shall employ a sufficient number of qualified medical technologists, or where appropriate, cytotechnologists, to perform proficiently under general supervision the clinical laboratory tests which require the exercise of independent judgment as follows:

(1) The medical technologists shall perform tests which require the exercise of independent judgment and responsibility, with a minimal supervision by the director or supervisor, in only those specialties or subspecialties in which they are qualified by education, training and experience.

(2) With respect to specialties in which the medical technologist is not qualified by education, training or experience, he shall function only under direct supervision and perform only tests which require limited technical skill and responsibility.

(3) Clinical laboratory technologists shall be sufficient in number to adequately supervise the work of technicians and trainees.

(4) An individual who qualifies as a cytotechnologist under subdivision (c) of this section may supervise technicians and trainees only in the specialty of cytology.

(b) Qualifications of medical technologist. A medical technologist must meet one of the following requirements:

(1) Successful completion of a full course of study which meets all academic requirements for a bachelor's degree in medical technology from an accredited college or university.

(2) Successful completion of three academic years of study (a minimum of 90 semester hours or equivalent) in an accredited college or university which met the specific requirements for entrance into, and the successful completion of a course of training of at least 12 months in a school of medical technology approved by the Council.
(3) Successful completion in an accredited college or university of a course of study which meets all academic requirements for a bachelor's degree in one of the chemical, physical or biological sciences and, in addition, at least one year of pertinent laboratory experience and/or training covering the specialty(ies) or subspecialty(ies) in which he performs tests, provided the combination has given the individual the equivalent in such specialty(ies) or subspecialty(ies) of the education and training described in paragraph (1) or (2) of this subdivision.

(4) Successful completion of three years (90 semester hours or equivalent) in an accredited college or university with a distribution of courses as shown below, and, in addition, successful experience and/or training covering several fields of medical laboratory work of such length (not less than one year), and of such quality that this experience or training, when combined with the education, will have provided the individual with education and training in medical technology equivalent to that described in paragraph (1) or (2) of this subdivision. Distribution of course work: (Where semester hours are stated, it is understood that the equivalent in quarter hours is equally acceptable. The specified courses must have included lecture and laboratory work. Survey courses are not acceptable.)

(i) for those whose training was completed prior to September 15, 1963: At least 24 semester hours in chemistry and biology courses of which not less than nine semester hours must have been in chemistry and must have included at least six semester hours in inorganic chemistry, and not less than 12 semester hours must have been in biology courses pertinent to medical sciences;

(ii) for those whose training was completed after September 15, 1963: 16 semester hours in chemistry courses, which included at least six semester hours in inorganic chemistry and are acceptable toward a major in chemistry; 16 semester hours in biology courses which are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and three semester hours of mathematics.

(5) With respect to individuals first qualifying prior to April 1, 1972, an exception to the requirements in paragraphs (1), (2), (3) or (4) of this subdivision may be made if:

(i) the technologist was performing the duties of a medical technologist at any time between July 1, 1961 and September 1, 1971;

(ii) the technologist has had at least 10 years of pertinent clinical laboratory experience prior to September 1, 1971: provided, that a minimum of 30
semester hours credit toward a bachelor’s degree from an accredited institution with a chemical, physical, or a biological science as his major subject; or 30 semester hours in an approved school of medical technology shall reduce the required years of experience by two years, with any additional hours further reducing the required years of experience at the rate of 15 hours for one year; and

(iii) he has performed the duties of a clinical laboratory technologist for at least two years during the qualifying 10 years:

(a) in a clinical laboratory having a director at the doctoral level, of a hospital, university, health department or medical research institution; or

(b) in a laboratory approved under the supplementary medical insurance program: Provided also, that where qualifying years in a laboratory described in clause (a) of this subparagraph are obtained after January 30, 1969, the laboratory meets applicable conditions under the Federal health insurance program, or under title 42, Code of Federal Regulations, part 74, the latter being the regulations issued pursuant to the Federal Clinical Laboratories Improvement Act of 1967.

(c) Qualifications of cytotechnologists:

(1) have successfully completed two years in an accredited college or university with at least 12 semester hours in biology courses pertinent to the medical sciences; and

(i) must have received 12 months of training in a school of cytotechnology approved by the American Medical Association; or

(ii) received six months formal training in a school of cytotechnology approved by the American Medical Association and six months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed such formal six months of training; or

(2) prior to September 1, 1971, shall have been graduated from high school, completed six months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology, and completed two years of full-time experience in cytotechnology.

58-1.6 Physical facilities. No specimen shall be examined unless the portion of the laboratory premises and the equipment used therein have been approved by the department as adequate for proper performance of the type of tests for which the laboratory is authorized.
58-1.7 Acceptance of specimens.

(a) No establishment other than a clinical laboratory under permit shall accept specimens for the purpose of obtaining information for the diagnosis, prevention, or treatment of a disease or the assessment of a health condition. This subdivision shall not be deemed to prohibit the acceptance of specimens solely for teaching and research purposes.

(b) Except as otherwise provided in section 58-1.9 of this Subpart, a clinical laboratory shall examine specimens only at the request of licensed physicians or other persons authorized by law to use the findings of laboratory examinations in their practice or in the performance of their official duties.

(1) If the request is oral, the physician or other authorized person shall submit a written request to the laboratory within 48 hours. If the laboratory does not receive the written request within that period, it shall note that fact in the record of daily accession.

(2) Other persons authorized by law to request the examination of specimens shall include but not be limited to:

(i) dentists and podiatrists, provided such examination is within the scope of practice of dentistry or podiatry;

(ii) chiropractors, provided such examination is within the scope of practice of chiropractic, as determined by the Executive Secretary of the State Board of Chiropractic, Cultural Education Center, Empire State Plaza, Albany, New York 12201;

(iii) physician's assistants, provided such examination is authorized by the supervising physician, and licensed midwives in accordance with their written protocols;

(iv) nurse practitioners, provided such examination is authorized under Article 139 of the State Education Law;

(v) police officers, provided such examination is incident to arrest charges for alcohol or drug impairment; and

(vi) judges ordering paternity tests under the Family Court Act.

(c)(1) A clinical laboratory under permit may operate one or more collecting or transfer stations, provided that it first obtains written approval from the commissioner for each proposed station.

(2) A collecting station is a facility, fixed or mobile, operated by a clinical
laboratory under permit, for the collection, drawing and/or temporary storage of materials derived from the human body, until forwarded to the clinical laboratory for testing.

(3) A transfer station is a fixed facility or a mobile courier service, operated by a clinical laboratory under permit, for the acceptance and/or temporary storage and/or transfer of materials derived from the human body, until forwarded to the clinical laboratory for testing.

(4) A temporary collecting station is a one-time, one-site facility, operated by a clinical laboratory under permit, with the prior approval of the department, which collects, draws and/or temporarily stores materials derived from the human body, as part of a health fair, health assessment or health risk reduction program, for the purpose of screening for health risk under a general order from a licensed physician-in-charge.

(5) A temporary collecting station may perform specific tests on-site with the prior approval of the department, including approval for testing, storage, transportation, record-keeping, and reporting protocols, provided that:

(i) all testing is performed under the active supervision of a clinical laboratory with a permit in the specific category of testing, provided that:

(a) such testing be limited to treatable diseases or those of public health significance and preventable by early detection; and

(b) the risks of erroneous results do not outweigh the benefits of testing.

(ii) the clinical laboratory can document that the testing method/technique is accurate, reliable, reproducible, and suitable for on-site use;

(iii) the clinical laboratory is responsible for adherence to all quality control/quality assurance procedures;

(iv) the physician-in-charge is responsible for assuring that participants with abnormal/at risk results are counseled appropriately and/or referred to a physician with pertinent materials for test interpretation;

(v) procedures exist to refer for follow-up those participants without a personal physician;

(vi) the screening is conducted to ensure an orderly flow of activities so that discussion of test results, under the direction of the physician-in-charge, takes place in an area suitable for confidential counseling without distraction; and
(vii) suitable procedures for safe collection and disposal of specimens are in place.

(6) Departmental approval to operate a collecting or transfer station must be renewed annually on July 1 in conjunction with the clinical laboratory's permit. Such application for approval must include the name and address of the permit laboratory and a protocol for operation of the station and for ensuring the security and integrity of the specimens collected. The department will conduct annual inspections of collecting stations.

(d) A collecting station or temporary collecting station shall:

(1) create and maintain a record of the daily accession of specimens containing the following information, except that a fixed station which accepts specimens from a mobile station may use a copy of the mobile station's accession record in lieu of creating its own for specimens provided by the mobile station:

(i) the name and address or other identification of the person from whom the specimen was taken;

(ii) the name and address or other identifier of the licensed physician or other authorized person who requested the test;

(iii) the date and hour when the specimen was taken;

(iv) the date and, if the test must be performed within 24 hours, the time the specimen was received in the collecting station;

(v) the type of test requested; and

(vi) the date and hour when each specimen was forwarded to the clinical laboratory for testing;

(2) forward a copy of the accession record to the clinical laboratory together with the specimens.

(e) Collecting stations, temporary collecting stations and transfer stations shall:

(1) have on their premises an operating refrigerator which:

(i) maintains a temperature range of 4 to 10 degrees Centigrade;

(ii) is equipped with an accurate thermometer; and

(iii) shall be used exclusively for the storage of patient specimens
for clinical laboratory testing;

(2) store each specimen requiring refrigeration in the refrigerator at all times until removed for forwarding to the clinical laboratory;

(3) store each specimen so as to maintain its original condition as much as possible, and assure that it will not become unsatisfactory as a patient specimen;

(4) forward specimens only to the clinical laboratory by which they are operated;

(5) transport, or arrange for the transportation of, each specimen which requires refrigeration, in a manner that will assure that its temperature will remain at between 4 and 10 degrees Centigrade until it reaches the clinical laboratory;

(6) transport, or arrange for the transportation of, all specimens not requiring refrigeration, so as to maintain their original condition as much as possible and assure that they will not become unsatisfactory as patient specimens; and

(7) transport, or arrange for the transportation of, all specimens in a manner designed to minimize the likelihood of exposing personnel or the public to any source of infection or hazard.

(f)(1) A mobile collecting station shall, in addition to complying with all requirements for fixed facilities, provide the department upon request with a monthly schedule in advance.

(2) A mobile collecting station, temporary collecting station or transfer station may use an alternative system of refrigerating specimens, provided that specimen temperatures are maintained at between 4 and 10 degrees Centigrade and the system's temperature is monitored and recorded periodically whenever in use.

(g)(1) No tests on specimens, whether human, veterinary, environmental or other, shall be performed in a collecting or transfer station except for:

(i) the screening or glucose and/or ketones in a collecting station, which must be performed prior to the administration of glucose for a glucose tolerance test. If sugar or ketones are present, the physician ordering such a test must be advised and the collection of blood for the tests may not be performed without his or her approval. Such approval must be documented in the accession record; and

(ii) tests performed in temporary collecting stations pursuant to section 58-1.7(c)(4) of this Part.

(2) Processing of specimens in a collecting, temporary collecting or
transfer station shall be restricted to the preparation of specimens for transport solely to
preserve their integrity and reliability. Such preparation shall include, but not be limited
to, centrifugation, separation of serum, freezing, refrigeration of specimens, and air
drying, fixing and/or freezing of smears.

(h) A clinical laboratory shall, at any time when a collecting station, temporary
collecting station, or transfer station it operates is open, permit the inspection of said
station by a representative of the department.

(i) The collecting station, temporary collecting station, or transfer station shall be
identified by the name of the clinical laboratory. The collecting station, temporary
collecting station, or transfer station must post conspicuously, in the waiting area or
other place visible to all visitors, a sign which states:

(1) the services at the site are limited to collection of specimens and/or
preparation of the specimens for transport;

(2) the name and address of the laboratory which will test the specimens;

(3) information on billing practices, including the name and address of the
establishment from which bills will originate and to which billing questions can be
directed.

(j) Collecting stations, temporary collecting stations, and transfer stations shall
be operated in such a way that no violation of article 38 of the General Business Law
takes place.

(k) The aforesaid written approval of the commissioner may be revoked,
suspended, limited or annulled as to any or all of the collecting stations, temporary
collecting stations or transfer stations operated by a clinical laboratory under permit on
proof that any one of said stations has been operated in violation of this Subpart, the
Sanitary Code contained in Chapter I of this Title, or article 38 of the General Business
Law. The enforcement provisions applicable to laboratory permits in subdivisions 2, 3
and 4 of section 577 of the Public Health Law shall also apply to such proceedings. In
addition, in the event of a violation, the laboratory permit of the clinical laboratory
operating the collecting station, temporary collecting station, or transfer station may be
revoked, suspended, limited or annulled pursuant to paragraph (g) of subdivision 1 of
section 577 of the Public Health Law.

58-1.8 Results of tests to be reported only to physicians or other
authorized persons. No person shall report the result of any test, examination or
analysis of a specimen submitted for evidence of human disease or medical condition
except to a physician, his agent, or other person authorized by law to employ the results
thereof in the conduct of his practice or in the fulfillment of his official duties. Reports shall not be issued to the patients concerned except with the written consent of the physician or other authorized person, except that information concerning blood type and Rh type factor may be provided in writing to the individual whose blood was testing without the consent of the individual's physician.

58-1.9 Testing to be done on premises except in certain instances. All specimens accepted by a laboratory for specified tests shall be tested on its premises. However, specimens for infrequently performed tests or those not included within specialties or subspecialties stated on its permit or those requiring specialized equipment and skill may be forwarded to and accepted by another laboratory under permit issued by the commissioner or to a laboratory which is operated by a government agency or a nonprofit research institution or to any other laboratory approved by the department. The reports of the results of such tests shall be sent by the testing laboratory to the forwarding laboratory, except that the forwarding laboratory may authorize the testing laboratory to send the report directly to the physician or other authorized person who requested the test, in which event the testing laboratory shall send a duplicate of the said report to the forwarding laboratory. Where the results of a test have been reported to it by the testing laboratory, the forwarding laboratory shall send a transcript of such report to the physician or other authorized person who requested the test and shall indicate thereon the name of the laboratory actually performing the test. In no event shall any report of the result of any test or transcript thereof be sent to the patient concerned except with the written consent of the physician or other authorized person who requested the test.

58-1.10 Specimens: identification and examination.

(a) Every specimen received for testing shall be numbered or otherwise appropriately identified and listed in an accession book, or another system acceptable to the department.

(b) Every tissue specimen shall be examined and reported upon by a qualified pathologist who is certified or eligible for certification for pathologic anatomy by the American Board of Pathology or whose qualifications, in the opinion of the Public Health Council pursuant to Part 19 of this Title, are equivalent of such certification. Preliminary examination or "screening" of specimens for cytopathology may be made only by an individual who has had special training acceptable to the department.

(c) A clinical laboratory or blood bank shall at any time during its regular working hours permit the inspection of its premises and records by a representative of the department and shall examine and report promptly on all specimens submitted by the department for the purpose of determining the competency of the laboratory.
(d) If the component to be tested for in a specimen is perishable, labile, or otherwise subject to deterioration, such specimen shall be tested as promptly as possible after collection. If a specimen is transported or stored, it shall be properly preserved, refrigerated, frozen or otherwise appropriately treated to maintain it in as close to its original state as is possible by then current technics.

(e) A specimen received by a laboratory shall not be tested or reported on if:

1. the apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested;

2. it has been collected, labeled, preserved or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen;

3. it is perishable and the time lapse between the collection of the specimen and its receipt by the laboratory is of such duration that the test finding may no longer be reliable; or

4. the date and, in the case of tests specified by the department, the hour when the specimen was taken by the physician or other authorized person is not furnished with the specimen.

(f) When a specimen is not tested for any of the reasons specified in subdivision (e) of this section the laboratory shall promptly notify the sender and give the reason therefor.

(g) All technical procedures employed in a laboratory shall be of proven reliability and generally accepted by leading authorities in the specialties of laboratory medicine and/or approved by the department.

58-1.11 Reports and records.

(a) When requested, a laboratory shall submit reports containing such information and data concerning its technical operation as may be specified by the department. Such reports shall be signed both by the owner and director of the laboratory.

(b) Each clinical laboratory or blood bank shall have records indicating the daily accession of specimens and containing the following information:

1. The laboratory shall have an accession system which may be a computerized accession system. It shall include:

   (i) the accession number or other identification of the specimen;
(ii) the name or other identification of the person from whom the specimen was taken;

(iii) the date the specimen was received in the laboratory;

(iv) the test or tests requested for that specimen;

(v) if the request for the test was oral and, contrary to the requirements of subdivision (b) of section 58-1.7 of this Subpart, the request was not followed by a written request, a statement to that effect, provided that, in the case of a computerized accession system, such a statement may be recorded in a separate accession log;

(vi) in the event a specimen is forwarded to another clinical laboratory for tests, the name of such other laboratory, the date upon which the specimen was forwarded, the date it was tested or the result or results were reported, and the date the report of findings was received from such laboratory, provided that, in the case of a computerized accession system, such information may be recorded in a separate accession log;

(vii) a brief description of the condition of unsatisfactory specimens when received, for example, broken, leaked, hemolyzed, turbid, etc.; provided that, in the case of a computerized accession system such information may be recorded in the laboratory report required by paragraph (2) of this subdivision;

(viii) if the specimen is not received from another laboratory either:

(a) the date the specimen was tested; or

(b) the date the result was reported, provided that the testing date or dates are available upon the request of the originating physician for the same period of time specified in subdivision (c) of this section for the retention of the report, unless the information required by clause (a) and (b) is recorded in the laboratory report required by paragraph (2) of this subdivision;

(ix) the hour, if required, when the specimen was received in the laboratory, unless such information is recorded in the laboratory report required by paragraph (2) of this subdivision;

(x) the name of the licensed physician or other authorized person or clinical laboratory or blood bank submitting the specimen, unless such information is recorded in the laboratory report required by paragraph (2) of this subdivision;
(xi) where a computerized accession system is in use, hard copy (computer generated) accession records shall be available to the laboratory staff or other authorized person in the laboratory for three months from the receipt of the specimen and shall contain all information required by paragraph (1) of this subdivision to be recorded in a computerized accession system.

(2) Each clinical laboratory or blood bank shall produce a laboratory report and shall supply the original of said report to the physician or other authorized person submitting each specimen for analysis. Each laboratory shall retain a duplicate copy of the report. Pathology reports shall utilize an accepted system of disease nomenclature. Each report shall contain the following information:

(i) patient name or other identification and the name of the person or institution referring the specimen;

(ii) the result of the laboratory test or tests;

(iii) the date, and hour if required, when the specimen was originally collected by the physician or other authorized person;

(iv) the name under which the laboratory has been issued a permit and its address;

(v) any information required to be recorded by paragraph (1) of this subdivision;

(vi) reports including numerical results shall include normal values, reference intervals, or similar method for identifying abnormal values. Alternative procedures other than reporting these values on the report may be approved by the department; and

(vii) if the specimen is received from another laboratory, either the date the specimen was tested or the date the result was reported, provided that the testing date or dates are available upon request of the originating physician or forwarding laboratory for the same period of time specified in subdivision (c) of this section.

(c) All records and reports of tests performed including the original or duplicates of original reports received from another laboratory shall be kept on the premises of both laboratories and shall be exhibited to representatives of the department on request. Records listed below shall be retained by the laboratory for at least the period specified. If other New York State or Federal regulations or statutes require retention for different periods of time, the laboratory shall retain the appropriate record for the longest period applicable. Records shall be retained in their original form for a period of
three months and may thereafter be stored on microfilm, microfiche, or other photographic record, or as magnetic tapes or other media in an electronic data processing system. Such records shall be adequately protected against destruction, either by archival storage or duplicated photographic or electronic medium or by other suitable means providing equivalent protection. Records which are required to be retained for more than two years may, after two years, be stored off the immediate laboratory premises, provided they can be available to the laboratory staff or other authorized person in the laboratory within 24 hours of a request for records.

(1) Requests for tests shall be retained for the same period of time as required for the test results or seven years, whichever is less, except that referral information for cytogenetic cases shall be retained for six years.

(2) Accession records shall be retained for seven years.

(3) Records of quality control results shall be retained for two years.

(4) Preventative maintenance, service and repair records shall be retained for as long as the instrument remains in use, except that records of monitoring of temperature-controlled spaces shall be kept for one year.

(5) The following types of laboratory reports shall be retained for at least the period specified;

(i) tissue pathology including exfoliative cytology - 20 years;

(ii) syphilis serology - negative report - two years;

(iii) cytogenetics - 25 years; and

(iv) all others - 7 years.

(6) Worksheets containing instrument readings and/or personal observations upon which the outcome is based shall be retained for one year.

(d) The following requirements shall apply to the retention and disposition of specimens:

(1) Specimens shall be retained so as to be accessible to the laboratory within 24 hours for at least the period set forth below:

(i) blood film - other than routine - 1 year;

(ii) blood film - routine - 6 months;

(iii) bacteriology slide on which a diagnosis depends - 1 year;
(iv) cytology slide showing any abnormality - 7 years;
(v) cytology slide showing no abnormality - 3 years;
(vi) tissue block - 20 years;
(vii) histopathology block - 20 years;
(viii) histopathology slide - 20 years;
(ix) bone marrow biopsy - 20 years;
(x) cytogenetic slide - 6 years;
(xi) photographic slide of cytogenetic karyotype - 25 years; and
(xii) recipient blood specimens - 1 week stoppered at 6 degrees Celsius.

(2) All specimens shall be disposed of in a manner designed to minimize the likelihood of causing infection to any member of the public or laboratory staff. The laboratory shall have a written protocol which shall be available to the department for inspection, describing its procedures for the disposal of specimens.

58-1.12 Cytopathology standards and quality assurance.

(a) Definitions.

(1) Examination means the initial review or screening of cytopathology samples by a cytotechnologist to determine if the sample is negative, abnormal or questionable, and shall include the marking of potentially abnormal cells and completion of laboratory records.

(2) Re-examination means the review of slides which have been examined or screened as normal. The selection of these slides must be made based on a protocol, available in the laboratory, which includes patient history, qualifications of the examining cytotechnologist, and source of referral.

(3) Facilitating means the preparation and review of non-gynecological slides by a cytotechnologist for diagnosis by a pathologist, and shall include the marking of abnormal cells and selection of representative slides.

(4) Quality control and quality assurance means those procedures and protocols, including re-examination, in place in the laboratory to assure consistency,
reliability, documentation and accuracy of results reported, and shall include corrective actions taken in the event of laboratory error.

  (5) Cytotechnologist means a clinical laboratory professional specializing in the analysis of cytopathology samples, including Pap smears, for cervical cancer and other diseases, who meets the qualifications specified by the department in section 58-1.5 of this Subpart. For purposes of the work standard in subdivision (b) below, this shall mean any person who is engaged in the initial examination of cytologic specimens. Cytopathologists who are engaged in initial examination of cytologic specimens need not register, but must maintain workload records and comply with workload standards.

  (6) Cytotechnologist work standard means a limitation on the number of Pap smears (also known as gynecologic slides) and non-gynecologic slides which a cytotechnologist may examine or facilitate during a particular time period, or other limitation on the quantity, speed or manner of examination of slides by a cytotechnologist.

  (7) Employ means to employ or contract with a cytotechnologist to examine cytological materials, including gynecologic and non-gynecologic slides.

  (8) Part-time means working less than a seven-and-one-half or an eight-hour day for a particular employer.

  (9) Clinical laboratory means a clinical laboratory licensed by the Department of Health of the City of New York or by the New York State Department of Health.

  (10) Work day means a twenty-four-hour period during which a cytotechnologist examines cytological materials for a clinical laboratory.

  (11) Work month means a calendar month during which a cytotechnologist examines cytological materials, including gynecologic slides, for a clinical laboratory.

  (12) Non-gynecological slide means a slide containing material obtained from other than the cervical-vaginal area. For each non-gynecologic case for which up to three slides are submitted, each of the slides shall count as one toward the work standard. For each non-gynecologic case for which more than three slides are submitted, only the first three shall be counted toward the work standard.

  (13) Total hours worked means the time spent during each work day at all employers examining slides and performing ancillary duties as defined in section 58-
1.12(b)(3) of this Subpart. For part-time cytotechnologists, the denominator shall be based on a seven-and-one-half or an eight-hour day adjusted as described in section 58-1.2(b)(3) and (4) of this section.

(b) Cytotechnologist work standard.

(1) No cytotechnologist shall exceed the applicable cytotechnologist work standard. No clinical laboratory shall require, authorize, encourage or permit any cytotechnologist to exceed the applicable cytotechnologist work standard. In determining whether a cytotechnologist exceeds the applicable cytotechnologist work standard, all work performed by the cytotechnologist during a given work day shall be considered, without regard to the clinical laboratory or other person for which it was performed.

(2) Unless otherwise provided, a cytotechnologist may examine no more than eighty one-slide gynecologic cases or fifty two-slide gynecologic cases per work day. If a cytotechnologist also examines non-gynecologic slides in a given work day, the cytotechnologist's workload for gynecologic slides shall be correspondingly reduced, in accordance with written guidelines prepared by the clinical laboratory and filed with the department, so that a cytotechnologist examines no more than a combined total of one-hundred gynecologic and non-gynecologic slides per work day.

(3) If a cytotechnologist spends more than one hour per day at any laboratory performing duties not directly related to examination of slides, such as assisting in fine needle aspirations, staining and preparation of slides, quality control and quality assurance activities, reporting test results, training, continuing education and routine clerical work, the laboratory director must decrease that cytotechnologist's workload and hours spent in screening.

(4) When a cytotechnologist works part-time or performs duties other than slide examination, the slide limit must be prorated using one or more of the following formulas:

(i) screening one-slide gynecologic cases:

\[
\frac{\text{hours worked on slides}}{\text{total hours worked in a work day}} \times 80 \text{ (cases)}
\]

(ii) screening two-slide gynecologic cases:

\[
\frac{\text{hours worked on slides}}{\text{total hours worked in a work day}} \times 50 \text{ (cases)}
\]
(iii) facilitating non-gynecologic cases (up to three slides):

\[
\text{hours worked on slides} \times 30 \text{ (cases)} \\
\text{total hours worked in a work day}
\]

(5) In no case shall the hourly rate of examination exceed 12.5 slides per hour per cytotechnologist, unless the laboratory has the department's approval for individual cytotechnologists to exceed this limit.

(6) The laboratory must provide rest periods and breaks as needed by the cytotechnologist.

(7) Exceptions.

(i) Each laboratory shall evaluate the performance of each cytotechnologist providing services to it, and establish an appropriate examination volume limitation based on the cytotechnologist’s experience, documented accuracy and performance in proficiency testing, or on other reasons, including false-negative or false-positive interpretations. Under no circumstances shall this volume be exceeded, even if it is lower than the maximum work standard.

(ii) A cytotechnologist may exceed the work standard by twenty (20) percent, with the written approval of the department. The laboratory director may request such approval based on each cytotechnologist's experience, documented accuracy, including false-negative or false-positive interpretations, and a performance score in proficiency testing of not more than two (2) errors. Documentation of department approval shall be available in the laboratory, and may be revoked by the department with prior notice to the laboratory, based on a cytotechnologist's performance in proficiency testing or other evidence that the cytotechnologist's accuracy is other than acceptable. The laboratory director shall monitor the performance of each cytotechnologist and advise the department whenever the approval is to be revoked based on on-the-job performance.

(iii) Cytotechnologists who qualify as supervisors under section 58-1.4 of this Subpart may re-examine up to twenty (20) slides per day in addition to the workload standard, provided the combined total number of slides does not exceed one-hundred (100), as part of the quality assurance program of the laboratory, with the prior approval of the department, based on documented accuracy, including false-negative and false-positive interpretations, and performance in proficiency testing. Such approval may be revoked, with prior notice to the laboratory, based on proficiency testing performance or other evidence that the cytotechnologist's accuracy is other than acceptable. Records shall be maintained to document the examination volume and hours worked by each cytotechnologist.
(iv) The department may increase the cytotechnologist work standard beyond the level already authorized elsewhere in this section for cytotechnologists using a federal Food and Drug Administration (FDA)-approved device in the preparation or examination of cytology slides:

(a) in determining whether to increase the cytotechnologist work standard with respect to a particular device, the department shall consider the following: the FDA’s approved use of the device; studies of the accuracy, reliability and appropriate use of the device; input from clinical laboratories using the device; recommendations of experts in the field of cytology and/or cytotechnology; and other relevant information as appropriate;

(b) (1) the department may require a clinical laboratory wishing to exceed the cytotechnologist work standard set forth elsewhere in this section to request in writing the department’s approval. The department may also require the applicant laboratory to provide, in a form acceptable to the department, some or all of the following information regarding the device in use at the laboratory: the device manufacturer’s recommendations, if any, regarding the quantity (i.e., slide volume), speed or manner of slide examination, and the basis for such recommendations; documentation of training for each cytotechnologist using the device; each cytotechnologist’s experience using the device, including false-negative and false-positive interpretations, workload, and number of hours spent examining slides; each cytotechnologist’s performance on proficiency testing; as well as any other information as determined appropriate by the department to assess device capacity and user capability; and

(2) the department shall provide written notice of the authorized work standard established pursuant to this subparagraph. The department may set a work standard in writing that applies to one or more cytotechnologists.

(c) laboratories shall maintain documentation of approval pursuant to this subparagraph for a minimum of two (2) years after use of the device is discontinued;

(d) if the department determines that a cytotechnologist work standard authorized pursuant to this subparagraph increases the rate of errors or compromises the reliability of results, the department shall adjust the standard as it deems appropriate and shall notify the affected clinical laboratories in writing of such change. Clinical laboratories that find the adjustment unacceptable may only request in writing that the department reconsider its determination; and

(e) notwithstanding the foregoing, any cytotechnologist work standard authorized by the department pursuant to this subparagraph shall be at least as stringent as the federal standards promulgated under the federal clinical laboratory improvement amendments of nineteen hundred and eighty-eight (1988) and/or other applicable law(s).
(c) Regularly scheduled education programs, averaging two hours per month, must be provided to the cytotechnologists and records thereof maintained.

(d) Record-keeping.

(1) Each clinical laboratory shall maintain records on work standards for three years, in a form approved by the department, which set forth, for each cytotechnologist employed by the clinical laboratory:

   (i) the name and registration number of the cytotechnologist;

   (ii) the number of hours worked by the cytotechnologist in each work day;

   (iii) the number of one-slide and two-slide gynecologic cases and non-gynecologic cases and slides examined by the cytotechnologist, as well as the total number of slides examined during each work day; and

   (iv) the actual hours worked, if required by the department, for any cytotechnologist working at more than one employer.

(2) Every cytopathology laboratory shall maintain, and make available to the department upon request, a calendar year workload report containing the following information for every cytotechnologist employed for any period of time during that calendar year:

   i) name of cytotechnologist;

   ii) registration number of cytotechnologist;

   iii) number of days worked and, for part-time cytotechnologists, full-day equivalent number calculated;

   iv) number of one-slide gynecologic cases read by the cytotechnologist;

   v) number of two-slide gynecologic cases read by the cytotechnologist; and

   vi) number of non-gynecologic cases read by the cytotechnologist.

(3) Every cytotechnologist shall maintain, and make available to the department upon request, a calendar year workload report containing the following
information for every cytopathology laboratory in which the cytotechnologist performed screening and/or facilitating during that calendar year:

i) name of laboratory;

ii) identification number of laboratory;

iii) number of days worked and, for part-time cytotechnologists, full-day equivalent number calculated;

iv) number of one-slide gynecologic cases read by the cytotechnologist;

v) number of two-slide gynecologic cases read by the cytotechnologist; and

vi) number of non-gynecologic cases read by the cytotechnologist.

(4) Each cytotechnologist shall maintain records on work standards for three years, in a form approved by the department, which set forth:

(i) the number of hours worked by the cytotechnologist in each work day;

(ii) the number of one-slide and two-slide gynecologic cases and non-gynecologic cases and slides examined, as well as the total number of slides examined during each work day;

(iii) the name and address of the clinical laboratory(ies) or other person(s) for whom the slides were examined;

(iv) the cytotechnologist registration number assigned by the department; and

(v) the actual hours worked at each employer, if required by the department.

(5) Records required to be maintained by clinical laboratories and cytotechnologists shall be made available for inspection and copying by the department upon request.

(6) Multiple employers. Whenever a cytotechnologist is employed by more than one clinical laboratory or other person during a work day, the cytotechnologist shall advise each clinical laboratory or person of any previous employment during the work day and the amount of work performed, to ensure that the
applicable cytotechnologist work standard is not exceeded.

(e) Standards for gynecologic slides.

(1) Each laboratory must establish a written protocol defining the standards to be used for determining if a slide is inadequate to test. These standards must be available in the laboratory and must be provided to each ordering physician or other practitioner.

(2) A gynecologic slide or a Pap smear shall not result in a diagnostic report if:

   (i) the apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested;

   (ii) it has been collected, labeled, preserved or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen;

   (iii) the slide is broken to such extent that it cannot be repaired adequately so that cells are not obscured or lost; and

   (iv) it contains insufficient cells or the cells are obscured by inflammation, blood, or lubricating ointment, so that an accurate diagnosis cannot be made.

(3) The laboratory shall note in the laboratory record and in the report to the physician the reason for the unsatisfactory evaluation. Such records must be available for inspection by the department. The total number of unsatisfactory smears should be reported to the department at least annually.

(4) If a slide is unsatisfactory under this subdivision, the clinical laboratory shall have an affirmative duty to advise the collecting physician or other practitioner that the slide or specimen is unsatisfactory and request the submission of a new slide. If the inadequacy is due to collection and preservation technique, the laboratory shall offer assistance to the practitioner in collection of adequate samples, free of contamination and foreign material.

(5) As minimum clinical information, the laboratory order form must request the patient’s date of onset of last menstrual period, age, previous abnormal cytology, and previous significant history.

(6) If the minimum required clinical information is not included on the order form or is otherwise unavailable, the laboratory must request this information. If the clinical information is not received, the laboratory record must be so noted and the report to the physician must state that the minimum required information was not provided.
(7) Slides from negative cases must be retained for at least five years and slides from cases with abnormalities must be retained for at least 10 years.

(8) Laboratory reports must identify the cytotechnologist and/or cytopathologist who diagnosed the case.

(f) Re-examination of slides.

(1) Each laboratory must establish a system for targeted re-examination of at least 10 percent of gynecologic slides determined to be not abnormal or questionable. Documentation of this system must be available in the laboratory for inspection by the department and to ordering physicians or other practitioners.

(2) Re-examination shall be based on prior cancer and other history of the patient, results of previous examinations, patient risk status as determined by the clinical physician, source of referral (i.e., practices and/or clinics with high-risk patients or high incidence or from geographical areas with high risk of disease). Re-examination shall also be performed on slides examined by new or inexperienced cytotechnologists and those determined to be in need of remediation based on proficiency testing performance. Records of this rescreening must be maintained for three years.

(3) In addition, laboratories employing more than one cytotechnologist must establish a system, which may be part of re-examination, to ensure the laboratory's consistency in examination of slides by two or more individuals or by the same individual on different occasions. Copies of the results must be maintained for three years and be available for inspection and copying by the department.

(4) All gynecologic cases which have been interpreted by a cytotechnologist as dysplasia, cervical intraepithelial neoplasia (CIN), carcinoma in situ (CIS) or malignancy and all non-gynecologic cases must be reviewed by a pathologist.

(5) Cases with abnormal findings as described in (4) above must be tracked by the laboratory and follow-up information, including results of subsequent biopsies, must be documented and available in the laboratory for twenty years.

(6) Records of recognized false-positive and false-negative cases must be maintained, including copies of subsequent biopsy reports, for twenty years, and be available to the department.

(g) Registration of cytotechnologists. All cytotechnologists, as defined in this Subpart, who are employed by a clinical laboratory must register with the department on the form provided by the department.
(2) The registration application must include the name and home address of the cytotechnologist; the name and address of all locations at which the cytotechnologist is employed as a cytotechnologist, regardless of whether the site or facility is under New York State or New York City permit; the cytotechnologist's working days and hours at each facility or site; the cytotechnologist's education and experience; the cytotechnologist's Social Security number as required under section 5 of the New York State Tax Law; and other information the department may require for enforcement of this Subpart.

(3) Within 30 days of a change in home address, employer or employer address, the cytotechnologist must notify the department on the form provided by the department.

(4) The department shall advise each cytotechnologist of the assigned registration number and provide an identification card to each cytotechnologist. The registration number must be used on all records, as required by the department. The registration card must be kept by the cytotechnologist and a copy must be maintained by each employing laboratory.

(5) No clinical laboratory shall employ a cytotechnologist unless the cytotechnologist is registered under this section. If the cytotechnologist is not registered at the time of hiring, an application for registration must be made within one week of commencing employment. When a cytotechnologist is hired, resigns or otherwise is separated from the laboratory, the laboratory director must so advise the department.

(6) A cytotechnologist's registration may be revoked, denied, suspended, or annulled upon falsification of information on the registration application, falsification of laboratory workload records, termination from a laboratory for cause, or other violation of the law, rules and regulations.

58-1.13 General requirements for performance of anatomic pathology and cytopathology procedures.

(a) Facilities.

(1) Laboratory space.

   (i) Work areas must be clean, well-lighted and well-ventilated;

   ii) utilities (water, gas, suction, electricity) must be available, as
needed;

(iii) microscopic work area, including space and furniture, must be conducive to high-quality performance;

(iv) cytopreparation area(s) must be separate from screening and clerical/secretarial area(s) so that personnel are protected from hazardous fumes and screening areas are free from distractions;

(v) there must be sufficient space for quality control, administrative, and clerical functions; and

(vi) storage of records and specimens must be in compliance with section 58-1.11 (c) and (d) of this Subpart.

(2) Safety precautions.

(i) Health and safety precautions comparable to those required in hospital laboratories must be maintained; and

(ii) universal precautions must be enforced when liquid specimens are handled.

(3) Equipment and reference resources.

(i) There must be an adequate number of high-quality, well-maintained binocular microscopes;

(ii) preventive maintenance of microscopes and other equipment must be performed, as recommended by the manufacturer, and documented in a log book; and

(iii) a core reference library should be conveniently available on the laboratory premises.

(4) Support personnel. There should be adequate clerical and laboratory assistance personnel, whose number and type are dependent on the volume of work.

(5) Salaries. The method of compensation should not adversely affect the quality of performance. Cytotechnologists should be free from quota or other pressures that limit appropriate slide review time.

(b) Laboratory operation.

(1) Specimens must be identified properly and must be accompanied by a complete test requisition containing minimal clinical information.
(2) A laboratory procedure manual describing the handling and storage of specimens from origination to final report, including collection, preservation, transportation, rescreening protocol and standards for specimens or slides, must be available in the work area.

(3) Solutions and stains.

   (i) Solutions and stains must be labelled to indicate concentration, expiration date, and storage requirements;

   (ii) stains must be monitored daily and written records thereon maintained;

   (iii) cross-contamination of specimens must be avoided. Non-gynecologic specimens must be stained separately from gynecologic specimens. Solutions must be filtered or replaced daily; particular care must be taken to filter solutions after processing body fluid specimens; and

   (iv) solutions and stains must be kept covered when not in use and stored at appropriate temperatures.

(4) Microscopy.

   (i) All microscopy must be performed on the laboratory premises; and

   (ii) cytotechnologist functions should include evaluation of the adequacy of specimens, marking of areas appropriate for further review, and rendering of a provisional interpretation.

(c) Special requirements for histopathology, oral pathology and dermatopathology.

   (1) All special stains shall be controlled for intended reactivity by the use of positive tissue sections, processed at the same time as the unknown tissue sections. Acid-fast staining procedures must include both a positive and a negative control slide.

   (2) All unprocessed remnants of tissue specimens shall be retained in a fixative solution until the portions submitted for microscopy have been examined and diagnosed by a pathologist.

   (3) Stained slides and paraffin blocks shall be retained for a minimum of 20 years from the date of examination.
(4) It is recommended that copies of reports be kept in numeric and alphabetic cross files. A numerical accession record satisfies the numeric file recommendation.

(5) Records must indicate the total number of blocks taken and the name of the pathologist who diagnosed the case.

(6) A duplicate copy of all reports, or the capability to reproduce the same, must be retained by the laboratory for 20 years.

(7) All slides referred for consultation must have the patient's name and other identifiers written on the label.